Check the Bair Hugger therapy website to ensure you have the most recent version of this document. www.bairhugger.com reorder #201031A

BAIR HUGGER OPERATOR'S MANUAL

Arizant Healthcare
bright ideas that work

Bair Hugger* Model 500/OR Temperature Management Unit

Operator's Manual

Table of Contents

3 Introduction

3 Description of the Total Temperature Management* System

3 Indications for Use

3 Contraindications

3 Warnings

3 Precautions

3 Important Information

4 Read Before Servicing Equipment

4 Setup and Operation

5 Temperature Management Units

6 Control Panel Features of the Model 500/OR Temperature Management Unit

7 Isolation Switch

7 Optional Features: IV Pole, Blanket Dispenser, Hose Assemblies

8 General Maintenance

8 Cabinet Cleaning

8 Technical Service and Order Placement

9 In-Warranty Repair and Exchange

9 When You Call for Technical Support

10 Specifications

12 Definition of Symbols

Introduction

Description of the Total Temperature Management System

The Bair Hugger brand Total Temperature Management system consists of a Bair Hugger forced-air temperature management unit (with available rolling stand and sheet clip) and Bair Hugger disposable components, including forced-air blankets and the 241* blood/fluid warming set. The system is intended for use in all clinical settings including the operating room.

This manual includes operating instructions and unit specifications for the Model 500/OR forced-air temperature management unit. For information about using Bair Hugger blankets or the 241 blood/fluid warming set with Bair Hugger units, refer to the "Instructions for Use" included with each of these disposable components.

Indications for Use

The Bair Hugger brand Total Temperature Management system is intended to prevent and treat hypothermia and to provide warmth to cold or shivering patients. In addition, the system should be used whenever conditions exist that could cause patients to become cold.

Contraindications

Do not apply heat to lower extremities during aortic cross-clamping. Thermal injury may occur if heat is applied to ischemic limbs.

Warnings

• Do not use Bair Hugger units with any forced-air blanket or cover other than Bair Hugger blankets. Thermal injury may result.
• Do not warm patients with the Bair Hugger unit hose alone. Thermal injury may result. Always attach the hose to a Bair Hugger blanket before providing skin surface warming therapy.
• Do not continue therapy if the Over Heat warning light illuminates and the audible alarm sounds. Thermal injury may result. Turn the temperature management OFF and contact qualified technical personnel. If using 241 fluid warming, immediately stop fluid flow and discard the fluid warming set.

Precautions

• Monitor the patient's temperature at least every 10 to 20 minutes, and monitor the patient's vital signs regularly. Reduce air temperature or discontinue therapy when the therapeutic goal is reached or if vital sign instability occurs. Notify physician immediately of vital sign instability.
• To prevent suffocation from misuse, do not leave children or infants unattended when administering Bair Hugger therapy.
• See CONTRAINDICATIONS and WARNINGS before administering therapy. Read this Operator's Manual, blanket instructions and 241 fluid warming set package instructions before use.

Important Information

EXPLOSION HAZARD

Do not use in the presence of flammable anesthetics.

ELECTRICAL SHOCK HAZARD

Do not disassemble the temperature management unit; refer to authorized technical personnel. There are electrically live parts within the unit when it is connected to the power source, even when the switches are in the OFF position.

ELECTRICAL INTERFERENCE

If radio frequency interference with monitoring equipment should occur, connect the temperature management unit to a different power source.

Read Before Servicing Equipment

The repair, calibration, and servicing of the temperature management unit requires the skill of qualified technical personnel who are familiar with good practice for medical device repair. If service is designated as not requiring the manufacturer's attention, the technical information is provided in the Service Manual or will be provided, upon request, by Arizant Healthcare Inc.

REFER TO SERVICE MANUAL

Perform all repairs and maintenance in accordance with the instructions in the Service Manual.

SAFETY INSPECTION

Perform a safety inspection after making repairs to the temperature management unit and before returning the unit to service. A safety inspection must include a test of the operating temperatures (described in the Service Manual), the Over Heat Alarm system, as well as a leakage current test.

PROPER USE AND MAINTENANCE

Arizant Healthcare Inc. assumes no responsibility for the reliability, performance, or safety of the equipment if:

- Modifications or repairs are performed by unauthorized personnel.
- The equipment is used in a manner other than that described in the Operation or Service Manuals.
- The equipment is installed in an environment that does not meet the relevant grounding requirements.

Setup and Operation

The Bair Hugger brand Total Temperature Management system is easy to set up and to use. Follow the instructions provided with each blanket for specific information.

1) Place the Bair Hugger blanket on the patient with the perforated side (the side with small holes) against the patient's skin.

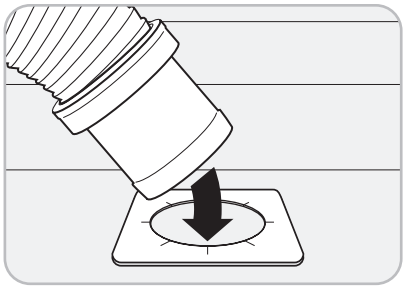


Figure A.

2) Insert the hose of the temperature management unit in the hose port on the blanket. Use a twisting motion to ensure a snug fit (see Figure A).

3) Connect the unit to a properly grounded power source.

4) Turn the Isolation Switch to the ON position (see the section titled *Isolation Switch*).

5) Press the System ON/OFF button to turn the unit ON and select the appropriate temperature setting.

6) Place a cotton blanket over the Bair Hugger blanket for maximum effectiveness.

7) Monitor the patient's temperature at least every 10 to 20 minutes and adjust the temperature setting of the unit as required.

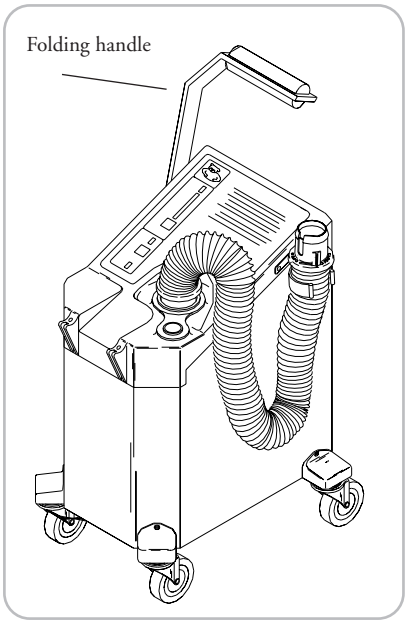


Figure B. Model 500/OR temperature management unit

Temperature Management Units

The temperature management unit uses a high-efficiency motor, a heating element, and a solid-state temperature control to create a continuous flow of warm air to the blanket. Model 500/OR is designed for safe use in all areas, including the operating room.

The folding handle on the Model 500/OR unit can be placed in two positions. The handle is moved forward and down for the folded position; it is pushed up and back for the upright position. In the folded position the unit can be rolled out of the way (for example, under the operating table) during warming therapy, and it can be stored more conveniently when warming therapy is completed. The upright position allows the unit to be easily transported between clinical areas.

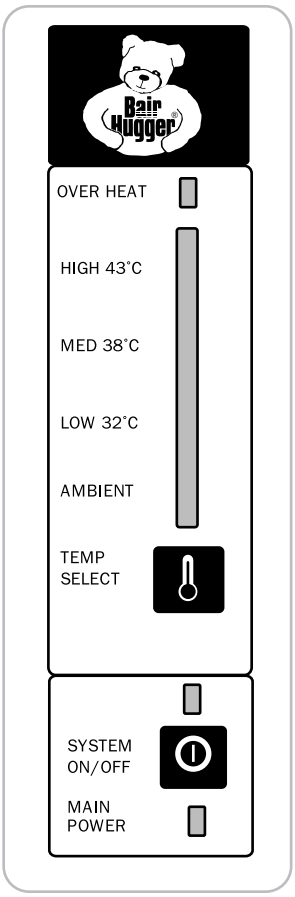


Figure C. Control panel of the Model 500/OR temperature management unit

Control Panel Features of the Model 500/OR Temperature Management Unit

OVER HEAT INDICATOR

The Over Heat Indicator illuminates and an audible alarm sounds when an over-temperature condition is detected. To reset, turn the unit OFF and then ON, either by the System ON/OFF button (see Figure C), or by the Isolation Switch (see the section titled *Isolation Switch.* Also refer to the *Warnings* section of this manual.)

TEMPERATURE INDICATORS

The indicator bar illuminates up to the selected temperature level. When the unit is initially turned on, the AMBIENT temperature level is automatically selected.

TEMPERATURE SELECT

Push this button to increase the temperature setting level by level to the desired setting. When the temperature setting is at HIGH, push the button again to return the setting to AMBIENT.

SYSTEM ON/OFF

Push this button to turn the unit either ON or OFF. The indicator directly above the switch illuminates when the unit is ON.

MAIN POWER INDICATOR

The main power indicator illuminates when main power is applied to the unit and the Isolation Switch is in the ON position (see the section titled *Isolation Switch*). This indicator must be illuminated for any functions to operate.

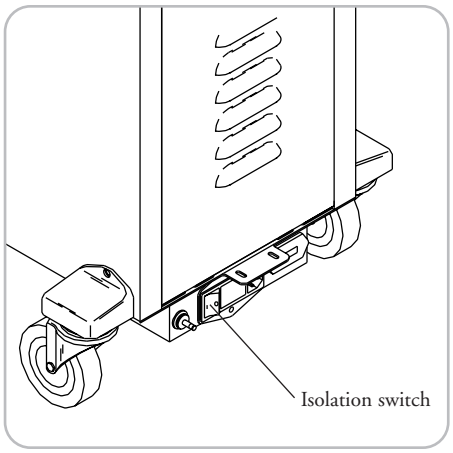


Figure D. Isolation Switch on the Model 500/OR unit

Isolation Switch

The isolation switch allows you to disconnect the temperature management unit from the power source without removing the power cord from the wall receptacle. The isolation switch is located on the back of the Model 500/OR unit. The isolation switch must be in the ON position before the unit will operate.

Optional Features

This section discusses optional features for Bair Hugger temperature management units. For more details about these features, please call Arizant Healthcare Inc. or your local distributor.

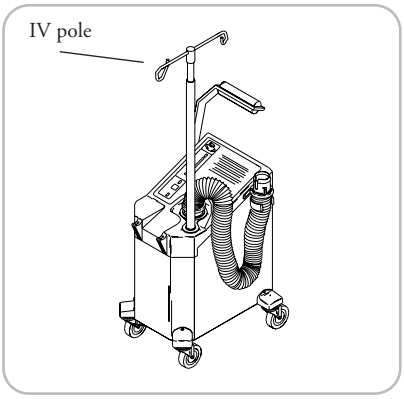


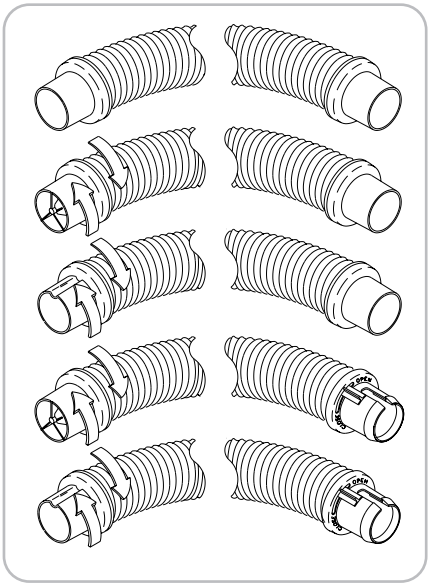
Figure E. Temperature management unit with IV pole option

IV Pole

Model 500/OR unit has a port that accommodates an Arizant Healthcare™ IV pole.

BLANKET DISPENSER

The blanket dispenser is available for use on the Series 500 units. This dispenser attaches to the unit and can store several Bair Hugger blankets. See the package instructions for details.



Standard length without swivel option (replacement only)

Standard length with swivel option (replacement only)

Extended length with swivel option (note keyway)

Standard length 241 fluid warming hose (replacement for 500 series only)

Extended length 241 fluid warming hose (note keyway) (standard for 500 series only)

Figure F. Hose assemblies

HOSE ASSEMBLIES

Temperature management hose assemblies are available in five options. The keyway on the extended length hose matches a keyway on units specifically calibrated for the extended length hose option, to ensure the delivery of proper temperature to the patient.

General Maintenance

Cabinet Cleaning

1) Disconnect the temperature management unit from the power source before cleaning.

2) Use a damp soft cloth and a mild detergent to clean the unit cabinet. Dry with a separate soft cloth.

CAUTION

• Do not use a dripping wet cloth to clean the cabinet. Moisture may seep into the electrical contacts, damaging the components.

• Do not use alcohol or other solvents to clean the cabinet. Solvents may damage the labels and other plastic parts.

Technical Service and Order Placement

USA, WORLDWIDE
TEL: 1-952-947-1200
1-800-733-7775
FAX: 1-952-947-1400

WITHIN EUROPE
TEL: +49-4154-9934-0
0800-100-1236 (Toll-free in Germany)
FAX: +49-4154-9934-20
0800-100-1324 (Toll-free in Germany)

In-Warranty Repair and Exchange

Replacement parts to correct a problem are delivered at no charge. To return a device to Arizant Healthcare Inc. for service, first obtain a Return Authorization (RA) number from a technical service representative. Please use this number on all correspondence when returning a device for service. A shipping carton will be delivered to you at no charge, if needed. Call your local supplier or sales representative to inquire about loaner devices while your device is being serviced.

When You Call for Technical Support

Remember, we will need to know the serial number of your unit when you call us. On the Model 500/OR unit the serial number label is affixed to the galvanized pan on the underside of the unit.

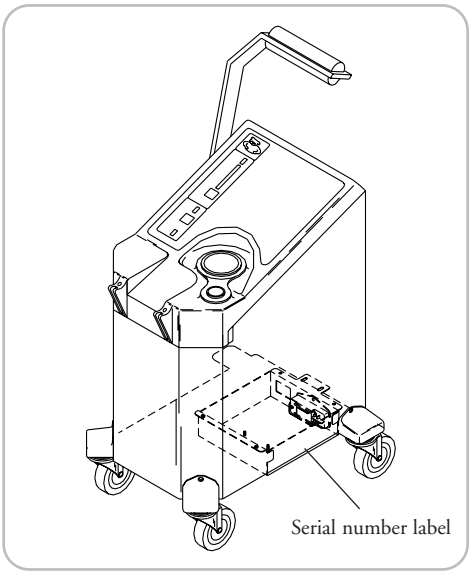


Figure G. Serial number label on Model 500/OR

Specifications

500/OR

Physical Characteristics

DIMENSIONS	24 in. high x 16 in. deep x 14 in. wide 61 cm high x 41 cm deep x 36 cm wide
WEIGHT	43 lb; 19.5 kg
MOUNTING	Supplied with swivel casters; floor use only
RELATIVE NOISE LEVEL	52 decibels
HOSE	Detachable, flexible, washable; compatible with the 241 fluid warming system
FILTRATION SYSTEM	0.2µM level
RECOMMENDED FILTER CHANGE	Every 6 months or 500 hours of use

Temperature Characteristics

TEMPERATURE CONTROL	Electronically controlled using a thermocouple sensor
HEAT GENERATED	1800 BTUs (average)
SYSTEM TIME TO 100°F (37.7°C)	~35 secs
OPERATING TEMPERATURES	*Air temperatures reaching the patient are approximately 2°C lower than the listed temperatures.* Average temperatures at the end of the hose, assuming the back pressure of a Bair Hugger warming blanket, or an Arizant Healthcare temperature test unit: HIGH: 43° ± 3°C 109.4° ± 5.4°F MED: 38° ± 3°C 100.4° ± 5.4°F LOW: 32° ± 3°C 89.6° ± 5.4°F

Safety System

THERMOSTAT	Independent bulb and capillary
OVERCURRENT PROTECTION	Dual fused input lines
ALARM SYSTEM	Over-heat: flashing red light with audible alarm; heater shuts down
CERTIFICATIONS	UL 544, CSA C22.2 No. 125, IEC 601-1, IEC 601-1-2, EN55014, AS 3200.1990
CLASSIFICATION	Classified under IEC 601-1 Guidelines as Class I, Type BF, Ordinary equipment, Continuous operation

Electrical Characteristics

BLOWER MOTOR	Operating speed: 2650 rpm Airflow: 28-30 cfm
POWER CONSUMPTION	Peak: 1000W Average: 500W
LEAKAGE CURRENT	<100µA
HEATING ELEMENT	850W Resistive
POWER CORD	15-foot, SJT, 3 cond., 10A 4.6 meter, HAR, 3 cond., 10A
DEVICE RATINGS	110-120 VAC, 60 Hz, 9.5 Amperes, or 220-240 VAC, 50 Hz, 4.5 Amperes, or 100 VAC, 50/60 Hz, 10 Amperes
FUSES	10A, 200mA and 500mA (110 - 120 VAC Units) 6.3A, 100mA and 500mA (220 - 240 VAC Units) 10A, 160mA and 400mA (100 VAC Units)
DIAGNOSTICS	Over-heat test can be performed by the biomedical group.

Definition of Symbols

ON/STANDBY

ON (used on isolation switch)

OFF (used on isolation switch)

ON/OFF push button switch

Temperature Control

Equipotentiality plug (Ground)

Fuse

Attention (see appropriate documents)

Non Explosion-Proof

Dangerous Voltage

Type BF Equipment (patient applied)

Voltage, Alternating Current (AC)

BAIR HUGGER OPERATOR'S MANUAL

Arizant Healthcare
bright ideas that work

CE 0470

Authorized Representative in the European Community
(as defined in Article 14 of the Medical Device Directive: 93/42/EEC):
Actamed Limited, Calder Island Way, Wakefield, WF2 7AW,
United Kingdom • TEL + 44 1924 200550 • FAX + 44 1924 200518

©2003-2004 Arizant Healthcare Inc. All rights reserved.
10393 West 70th Street, Eden Prairie, MN 55344 USA
TEL 800-733-7775 • 952-947-1200 • FAX 800-775-0002 • 952-947-1400
www.arizanthealthcare.com

*Arizant, Arizant Healthcare, bright ideas that work, Bair Hugger, 241, Total Temperature Management, and the Bair Hugger and Arizant logos are trademarks of Arizant Healthcare Inc., registered or pending in the U.S. Patent & Trademark Office and in other countries.

Bair Hugger temperature management products may be covered by one or more of the following patents: US 6,355,915; 6,309,409; 6,309,408; 6,290,716; 6,287,327; 6,254,337; 6,241,755; 6,228,107; 6,210,428; 6,203,567; 6,176,870; 6,168,612; 6,146,412; 6,129,936; 6,126,681; 6,126,393; 6,036,722; 5,997,572; 5,968;084; 5,964,792; 5,928,274; 5,824,025; 5,800,489; 5,773,275; 5,733,318; 5,697,963; 5,674,269; 5,658,325; 5,620,482; 5,545,194; 5,405,371; 5,350,417; 5,336,250; 5,324,320; 5,300,102; 5,300,101; 5,184,612; 5,044,364; 4,572,188. Japan 2,561,326. Canada 1,325,484. EPO 0,311,336. Australia 756,900. Other patents pending.

201031A 04/04

Bair Hugger®